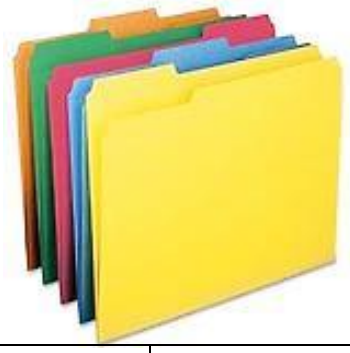
IRB PROCEDURE FLOW

1. ***IRB FORMS*** *will be sent to your email. Fill it up electronically the Review Checklist, Application Form, and other forms needed and* **SUBMIT ALL Basic Documents in 3 sets** *with the* ***prescribed folder*** *to commence the* **ASSESSMENT PROCEDURE.**

PLEASE BE GUIDED OF THE FOLLOWING:

1. Short Folder(paper) in 3 sets with colour coding (use fastener punch on the side):



COED	**BLUE**
MARITIME	**WHITE**
CBA	**YELLOW**
CCJE	**RED**
CEA	**MAROON**
NURSING	**GREEN**
CCS	**GRAY**
PHARMACY	**PURPLE**
DENTISTRY	**LAVENDER**
MEDICINE	**NEON GREEN**
GS – THESIS	**PINK**
GS – DISSERTATION	**BLACK**
CAS	**ORANGE**
NON-UV	**LIGHT GREEN**

2. Follow the sequence on arrangement as stated in the Review Checklist (UVIRB Form IIA 2015) in the Basic Documents needed.

Basic Documents (must submit) – 3 SETS (prescribed folder)

- ☐ 2 copies of the IRB Procedure

IRB PROCEDURE FLOW

- ☐ Review Checklist **[UVIRB FORM II (A) 2015]**
- ☐ Printed Registration and Application Form**[UVIRB FORM II (B) 2015]**
- ☐ Study Protocol (Chapter 1-3) for Quantitative studies and 1-2 for Qualitative Studies
- ☐ Complied Panel's Recommendations with signature of all panel members
- ☐ Records of Proceedings
- ☐ Letters to be given to the Institution/Organization
- ☐ Approved Letter for Design Hearing
- ☐ Approved Title Study
- ☐ Data Collection Forms/Questionnaire
- ☐ Diagrammatic Workflow
- ☐ CV of PI and study team members and adviser
- ☐ Proof of payment
  - Design hearing fee
  - Ethics review fee (as applicable)
- ☐ Technical Soundness: – IRB OFFICE
  - Research Protocol Assessment Form [UVIRB FORM II (C) 2015]
  - Quantitative Research - Form II (C) - 1
  - Qualitative Research – Form II (C) - 2
  - Research Agenda – Form II (C) – 3
- ☐ Ethical Soundness: (UVIRB FORM II (D) 2015) - IRB OFFICE
  - Ethical Consideration Assessment Form II (D) - 1
  - Inform Consent Assessment Form II (D) – 2

Study-specific Documents (submit as needed)

- ☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV)
- ☐ Informed Consent Assessment Form (for studies with human participants) **[UVIRB FORM II (D2) 2015]**
- ☐ Informed consent form in English (for studies with human participants)
- ☐ Informed consent form in local language (for studies with human participants)
- ☐ Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- ☐ Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)

IRB PROCEDURE FLOW

- ☐ Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team (for clinical trials)
- ☐ Recruitment advertisements (as needed by the study protocol)
- ☐ Other information or documents for participants (such as diaries, etc.)
- ☐ Material Transfer Agreement (for any research involving transfer of biological specimens)
- ☐ Memorandum of Agreement (for collaborative studies)
- ☐ Site Resources Checklist for Clinical Trial Outside UV By UV Personnel
- ☐ Site Resources Checklist for Clinical Trial Outside UV By non-UV Personnel
- ☐ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
- ☐ National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while UVIRB review is ongoing)
- ☐ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)

2. ***When Documents are complete……***
   a. IRB Assessment – 2 days (not included weekend & holiday)
   b. IRB Assessment result – 2nd day (you will be informed)
      i. Exemption – clearance will be given on the 3rd day
      ii. Expedited – 7 days (not included weekend & holiday)
         - Review Process Date:
         - Review starts after the payment date.
      iii. Full Board – once a month (3rd week)
         - Review Process Date:
            - Review starts will be 7 days after the payment date.
         - Requirements:
            - Power Point presentation
            - Appearance during full board meeting
            - Additional two (2) sets of study protocol

3. ***Process for Payment……***
   a. Ask form and blank receipt to be filled out – IRB office
   b. Pay to the accounting office

IRB PROCEDURE FLOW

c. Photocopy the form & machine validated receipt
d. Submit 5 photo copies of the receipt and payment form (in one page) and the original (yellow copy) of the receipt
e. Start counting the next day - DAY 1 PROCESSING
    - Full Board Review
        - Make sure to pay before 7 days of the date for full board review schedule.

(UV)	Undergraduate	Master's Thesis	Doctoral Dissertation
Exemption	100.00	100.00	100.00
Expedited	1, 500.00	2, 400.00	3, 000.00
Full Board	3, 000.00	4, 800.00	6, 000.00
Externally Funded	-	7, 000.00	10, 000.00
(NON - UV)	**Undergraduate**	**Master's Thesis**	**Doctoral Dissertation**
Exemption	1,500.00	-	-
Expedited	3, 000.00	7, 000.00	8, 000.00
Full Board	5, 500.00	10, 000.00	11, 000.00
Externally Funded	-	9, 000.00	12, 000.00

4. ***Resubmission***.....

A. Schedule:

Undergraduate

- 8:00AM – 12:00N, Monday, Tuesday & Thursday **(**Releasing and resubmission)

Graduate School

- 8:00AM – 5:00OM, Monday – Friday
- 8:00AM – 12:00N, Saturday

(Releasing and resubmission)

B. Requirements:

Graduate School and Undergraduate

IRB PROCEDURE FLOW

1. Let the adviser check and approve the revise study. Affix adviser's signature in the form.
2. Provide two (2) photocopies of the form.
   - 1st copy – attach to the revised protocol.
   - 2nd copy – Principal Investigator's copy.

5. Notice to Proceed

A. Schedule

1. Wednesday Morning & Friday Whole Day

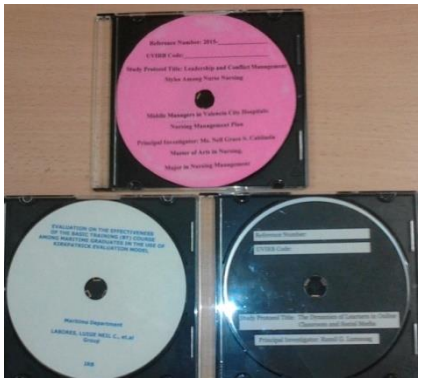
– Submission of NTP Requirements and Releasing of NTP.

B. Requirements

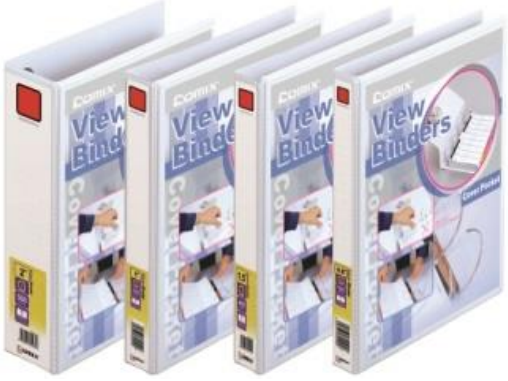
1. Send soft copy of the basic documents (refer to NTP Checklist) @ uvirb2015@gmail.com.

2. Submit the following:

2.1 CD – containing the basic documents (See sample)



2.2 COMIX VIEW BINDER (A4, 2.5", 3 HOLES)



2.3 Approved Final Copy

IRB PROCEDURE FLOW

Submit a final copy of the study protocol fastened on a prescribe folder containing the following:

2.3.1 Cover page
2.3.2 Table of contents
2.3.3 Chapter 1 – 3
2.3.4 References
2.3.5 Questionnaire
2.3.6 Appendices
2.3.7 CV (PI and Adviser)

C. Signing of the Certificate of Agreement

All members must be present during signing of the Certificate of Agreement.

1. *Terms and Condition of the* Certificate *of Agreement*

1.1 Full paper before signing Authority to Print

1.2 Hard copy of the protocol before signing the Clearance

1.3 Submits report immediately for any protocol deviation/violation

1.4 Progress report annually if study is not yet completed.

1.5 Renewal of IRB Notice to Proceed after validity date.

D. Releasing of Notice to Proceed

Notice to Proceed will be released to the Principal Investigator if above requirements is complied.

1. Terms and Conditions

1.1 Notice to Proceed is a legal document that allows the Principal Investigator to proceed in data collection as the study was approved and govern by UV-IRB. Any complaints made by the respondents of the study, they are advice to contact UV-IRB.

IRB PROCEDURE FLOW

1.2 If Notice to Proceed/ Certificate of Agreement will be loss by the Principal Investigator, second copy will be released provide to comply the following:

1.2.1 Request letter signed by the PI's adviser and Dean
1.2.2 Affidavit of Loss
1.2.3 Payment of the Certificate

I, _____affixed my signature as a proof that I had read, understand and agreed with the IRB procedure and requirements upon submission of my study protocol.

_____

Signature